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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/653,433 | 09/01/2000 | Zuzana Kossaczka | 2026-4298US | 5517 |

7590 04/30/2002
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EXAMINER

PORTNER, VIRGINIA ALLEN

| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 04/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,433

Applicant(s)

Kossaczka et al

Examiner

Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 1, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) 6-11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

Claims 1-15 are pending.

Claims 1-5 and 12-14 are under consideration.

Claims 6-11 and 15 are withdrawn from consideration.

Election/Restriction


1. Applicant's election without traverse of Group I, claims 1-5 and 12-14 in Paper No. 12 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed November 6, 2000 has been considered.

Double Patenting

3. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 44 of U.S. Patent No. (US Pat. 5,738,855).



Although the conflicting claims are not identical, they are not patentably distinct from each other because the now claimed Vi antigen may be obtained from any source as long as it is characterized as S.typhi Vi antigen, and the allowed claims recite a species of Vi antigen that is synthetic, or immunologically equivalent obtained from a plant or fruit. A genus claim is obvious over a species.

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Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1-2, 5 and 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Szu et al (December 8, 1997, different inventive entity).

7/a
The claimed invention is directed to a composition comprising a S.typhi Vi polysaccharide covalently linked to Pseudomonas aeruginosa recombinant exoprotein A through a carboxylic acid dihydrazide linker and a method of inducing an immune response in a human and a method of vaccinating a human against S.typhi, both methods comprising the step of administering the composition to a human.

(Composition) Szu et al disclose a composition comprising a S.typhi Vi polysaccharide covalently linked to Pseudomonas aeruginosa recombinant exoprotein a through a carboxylic acid dihydrazide linker, wherein the linker is identified by the abbreviation ADH.

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(Method) Szu et al also disclose a method of inducing an immune response in a human and a method of vaccinating a human against S.typhi, both methods comprising the step of administering the composition to a human, wherein the humans were children of 2-4 years old (see paragraphs 1-2).

Inherently the reference anticipates the now claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

6. Claims 1-5 and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Szu et al (October 17, 1994).

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The claimed invention is directed to a composition comprising a S.typhi Vi polysaccharide covalently linked to Pseudomonas aeruginosa recombinant exoprotein a through a carboxylic acid dihydrazide linker and a method of inducing an immune response in a human and a method of vaccinating a human against S.typhi, both methods comprising the step of administering the composition to a human.

(Composition) Szu et al disclose a a composition comprising a polysaccharide that has the equivalent immunoreactivity as that of S.typhi Vi polysaccharide antigen obtained from a different source, but antibodies stimulated to the polysaccharide specifically immunoreact with S.typhi Vi polysaccharide (see Table 2, col. 14, line 45; claims 40 and 49). The Vi same/equivalent antigen was covalently linked to Pseudomonas aeruginosa recombinant exoprotein a (see claim 44) through a carboxylic acid dihydrazide linker (see claim 14), wherein the linker is identified by the abbreviation ADH.

(Method) Szu et al also disclose a method of inducing an immune response in a human and a method of vaccinating a human against S.typhi, both methods comprising the step of administering the composition to a human, wherein the humans received a dose of about 25 micrograms (see col. 15, Example 7 and claim 49).

Inherently the reference anticipates the now claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious

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difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Fattom et al (1992, submitted in Applicant's PTO-1449) is being cited from showing the abbreviation "ADH" to mean adipic acid dihydrazide.

9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner

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can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

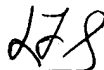
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

April 18, 2002



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600